

Food and Drug Administration, HHS

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treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(c) *Related tolerances.* See § 556.273 of this chapter.

(d) *Conditions of use.* It is used in the feed for cattle as follows:

(1) *Amount.* 1.1 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs and as an aid in control of sucking lice.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 30 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

(2) *Amount.* 2.3 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 10 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

[41 FR 11000, Mar. 15, 1976, as amended at 51 FR 7397, Mar. 3, 1986; 57 FR 7652, Mar. 4, 1992; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997]

§ 558.258 Fenbendazole.

(a) *Specifications.* Type A medicated articles: 4 percent (18.1 grams per pound (g/lb)), 8 percent (36.2 g/lb), and 20 percent (90.7 g/lb) fenbendazole.

(b) *Approvals.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use—(1) Turkeys.*

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
14.5 (16 parts per million).	Growing turkeys: For the removal and control of gastrointestinal worms: round worms, adult and larvae (<i>Ascaridia dissimilis</i>); cecal worms, adult and larvae (<i>Heterakis gallinarum</i>), an important vector of <i>Histomonas meleagridis</i> (Black-head).	Feed continuously as the sole ration for 6 days. For growing turkeys only.	057926

(2) Swine.

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period.	For the removal and control of: Adult stage lungworms (<i>Metastrongylus apri</i> and <i>M. pudendotectus</i>); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (<i>Ascaris suum</i>); adult stage nodular worms (<i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i>); adult stage small stomach worms (<i>Hyostrongylus rubidus</i>); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (<i>Trichuris suis</i>); adult and larvae kidney worms (<i>Stephanurus dentatus</i>).	Feed as sole ration	057926
(ii) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 20	As in paragraph (e)(2)(i) of this section; for increased rate of gain in growing-finishing swine.	Feed as sole ration. Do not feed to swine that weigh more than 250 pounds (lbs); lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 10 to 80 (to provide 9 mg/ kg of body weight).	Lincomycin 40	As in paragraph (e)(2)(i) of this section; for control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred.	Feed as sole ration. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926
(iv) 10 to 80 (to provide 9 mg/ kg of body weight).	Lincomycin 100	As in paragraph (e)(2)(i) of this section; for the treatment of swine dysentery.	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926
(v) 10 to 80 (to provide 9 mg/ kg of body weight).	Lincomycin 200	As in paragraph (e)(2)(i) of this section; for reduction in the severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> .	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pound (lb); lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926
(vi) 10 to 300 (to provide 9 mg/ kg of body weight).	Bacitracin methylene disalicylate 10 to 30.	Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency.	Feed as sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573
(vii) 10 to 300 (to provide 9 mg/ kg of body weight).	Bacitracin methylene disalicylate 250.	1. Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.	1. Growing/finishing swine: Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 lbs. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573
.....	2. Pregnant sows: As in paragraph (e)(2)(i) of this section; for control of clostridial enteritis in suckling pigs caused by <i>Clostridium perfringens</i> .	2. Pregnant sows: Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	

(3) Cattle—(i) Conditions of use are as follows:

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Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(A) 5 mg/kg body weight (2.27 mg/lb)		For the removal and control of lungworms (<i>Dictyocaulus viviparus</i>); barberpole worms (<i>Haemonchus contortus</i>); brown stomach worms (<i>Ostertagia ostertagi</i>); small stomach worms (<i>Trichostrongylus axei</i>); hookworms (<i>Bunostomum phlebotomum</i>); thread-necked intestinal worms (<i>Nematodirus helvetianus</i>); small intestinal worms (<i>Cooperia oncophora</i> and <i>C. punctata</i>), bankrupt worms (<i>Trichostrongylus colubriformis</i>), and nodular worms (<i>Oesophagostomum radiatum</i>).	Feed as sole ration for one day. Do not use within 13 days of slaughter.	057926
(B) 5 mg/kg body weight (2.27 mg/lb) in a free- choice feed		As in paragraph (e)(3)(i)(A) of this section.	Formulate as specified in paragraph (e)(3)(ii) of this section. Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Do not slaughter within 13 days following last treatment.	057926

(ii) *Formulate for use as a free-choice cattle feed as in paragraph (e)(3)(i)(B) of this section as follows:*

Ingredient ¹	Percent	International feed No.
(A) Ingredient:		
Copper sulfate	0.45	6-01-720
Dried Cane Molasses	3.12	4-04-695
Monosodium phosphate	31.16	6-04-288
Salt (sodium chloride)	59.00	6-04-152
Zinc sulfate	0.76	6-05-556
Fenbendazole Type A article (20%)	5.51	
(B) Ingredient:		
Dicalcium phosphate	32.31	6-00-080
Limestone	17.13	6-02-632

Ingredient ¹	Percent	International feed No.
Magnesium oxide	9.79	6-02-756
Zinc sulfate	1.47	6-05-556
Copper sulfate	0.29	6-01-720
Potassium iodide	0.0098	6-03-759
Dried Cane Molasses	0.98	4-04-695
Selenium	0.0002	
Salt	35.93	6-04-152
Fenbendazole Type A article (20%)	2.09	

¹The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium must comply with published regulations.

(4) *Horses.*

Amount fenbendazole in grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (<i>Strongylus edentatus</i> , <i>S. equinus</i> , <i>S. vulgaris</i> , <i>Triodontophorus</i> spp.), small strongyles (<i>Cyathostomum</i> spp., <i>Cylicocyclus</i> spp., <i>Cylicostephanus</i> spp.), and pinworms (<i>Oxyuris equi</i>); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (<i>Parascaris equorum</i>)..	Feed at the rate of 0. 1lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Do not use in horses intended for food..	057926
(ii) [Reserved]	

(5) *Zoo and wildlife animals.*

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine (<i>Sus scrofa</i>).	3 mg/kg/day for 3 days..	For the removal and control of kidney worm (<i>Stephanurus dentatus</i>), roundworm (<i>Ascaris suum</i>), nodular worm (<i>Oesophagostomum</i> <i>dentatum</i>).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae).	2.5 mg/kg/day for 3 days..	For the removal and control of small stomach worm (<i>Trichostrongylus</i> spp.), thread necked intestinal worm (<i>Nematodirus</i> spp.), barberpole worm (<i>Haemonchus</i> spp.), whipworm (<i>Trichuris</i> spp.).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926
(iii) Rocky moun- tain bighorn sheep (<i>Ovis c.</i> <i>canadensis</i>).	10 mg/kg/day for 3 days..	For the removal and control of <i>Protostrongylus</i> spp.	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926

[66 FR 58935, Nov. 26, 2001, as amended at 68 FR 34534, June 10, 2003]

§ 558.265 Halofuginone hydrobromide.

(a) *Approvals.* Type A medicated articles: 6 grams per kilogram (2.72 grams per pound) to 057926 in §510.600(c) of this chapter.

(b) *Related tolerances.* See §556.308 of this chapter.

(c) *Conditions of use.* (1) It is used in feed for broiler chickens as follows:

(i) *Amount.* 2.72 grams per ton.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bambermycins 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers.

(iii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for

increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(iv) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 to 15 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(v) *Amount per ton.* Halofuginone hydrobromide 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams and roxarsone 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain; and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; use as sole source of organic arsenic; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vi) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria*